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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,134

11/26/2003

Katherine M. Burnett

B100001XY

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09/21/2010

Glaxo Smith Kline

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EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

09/21/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,134	<b>Applicant(s)</b> BURNETT ET AL.	
	<b>Examiner</b> KENDRA D. CARTER	<b>Art Unit</b> 1627	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39,40,42,45,47,49-70,72,74-83 and 85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39,40,42,45,47,49-70,72,74-83 and 85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2010 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of July 16, 2010 made to the Board's decision filed May 18, 2010. Claims 39, 40, 42, 45, 47, 49-70, 72, 74-83 and 85 are pending. Claim 85 is new and claims 41, 44, 46, 48, 71, 76 and 84 are cancelled.

In light of the amendments to claim 72, all previously made 35 U.S.C. 103(a) rejections are withdrawn.

In light of the amendments to claims, the 35 U.S.C. 112, first paragraph and obviousness double patenting rejections over US Patent 6,238,683 are withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejections for claims 39, 40, 42, 45, 47, 49-70 and 74-83 were found not persuasive and thus upheld.

Due to the amendment to the claims, the new and modified rejections are made below. The Applicant's arguments are not addressed because the amendments to the claims are addressed in the new rejections.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not material affect the basic and novel characteristic(s)" of the claimed invention *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103 , absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps of materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**1) Claims 72 and 74-83 are rejected on the ground of nonstatutory double patenting over claims 3, 6, 8, 12-16 and 18-30 of U. S. Patent No. 7,179,475 B1 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.**

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an anhydrous gel composition consisting of propylene glycol, polyethylene glycol, glycerin, about 1 to about 50 percent by weight of ethanol, ketoconazole, PPG-15 stearyl ether, hydroxypropyl cellulose, ascorbic acid, butylated hydroxytoluene, citric acid and at least one colorant. The composition is used to treat seborheic dermatitis and skin fungal disorder associated with *T. rubrum* or *P. ovale*.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**2) Claims 39, 40, 42, 45, 49, 53, 54, 58, 62, 63, 65, 69 and 74-83 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4, 6, 8, 12-16 and 18-30 of U.S. Patent No. 7,179,475 B1.**

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The US Patent teach the same composition, amounts and methods except for the amount of polyethylene glycol and glycerin in a combined amount of about 10 to about 80 percent by weight.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the composition of the US Patent and the combined amounts of polyethylene glycol because the US Patent teach both components (see claims 1-3) and their individual amounts (see claims 8 and 12) that add up to the combined amount as claimed in the current invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**1) Claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent No. 5,993,787) in view of Shelton (US 4,083,956).**

Sun et al. teaches anhydrous topical preparations with good physical stability and excellent cosmetic attributes comprising propylene carbonate; one or more short chain alcohols and/or glycols, such as ethanol, isopropanol, propylene glycol, polyethylene glycol, etc; glycerol (glycerine); and an active ingredient (see Abstract, in particular.) The topical preparations are formulated as, e.g. gels (see column 3, lines 14-19, in particular.) Active ingredients are selected from antifungal agents, such as miconazole nitrate, ketoconazole, etc. (see column 6, lines 1-12, in particular.) Additional components, such as pigments, ascorbic acid, BHT, chelating agents, hydroxypropyl cellulose, etc. are taught to be useful therein (see column 4, lines 9-13, column 8, lines



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20-65 and column 9, lines 17-28, in particular.) Emollients such as Arlamol E® (PPG-15 Stearyl Ether) are also taught to be useful therein (see column 10, lines 61-67 and column 16, lines 19-37, in particular.) Antifungal agents (miconazole nitrate) are exemplified in concentrations of 2%; propylene glycol is exemplified at 20% BHT is exemplified at 0.05%; glycerol is exemplified at 20%; chelating agents are taught at 0.1-10%; PPG-15 stearyl ether is exemplified at 2%; and ethanol is exemplified at 55.875 by weight (i.e., about 50% by weight, as recited in the claims) (see column 8, lines 42-49 and column 10, line 32 through column 11, line 3, in particular.) Since the exemplified amounts of propylene glycol and glycerol are each 20%, the combined amount is within the claimed (see claim 39c) range of about 10 to about 80 % by weight. The treatment of athlete's foot (tinea pedis), ring worm (tinea corporis), jock itch (tinea cruris) and the administration to human skin is taught (see column 2, lines 38-58 and column 9, line 60 through column 10, line 5, in particular.) Use of compositions against *T. rubrum*, specifically, is also taught (see column 12, line 46 through column 14, line 5, in particular.) Sun et al. does not specifically exemplify the combinations as herein envisioned.

For clarification, the Examiner has cited Shelton to teach that propylene carbonate is a gel promoting agent that generally comprise from about 1.0% to 3.0% by weight of the composition (see column 4, lines 2-8).

Regarding the recitation that the composition "does not contain a retinoid or a steroid" as recited in claim 85, it is noted that Sun et al. teaches that the active ingredient can be an antifungal, and exemplifies compositions containing an antifungal agent (e.g. miconazole nitrate) that do not contain a steroid or a retinoid (see column 10, lines 30-68, in particular.) Thus, such compositions that do not contain a steroid or a retinoid are considered to be obvious over Sun et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a composition comprising the glycols and alcohols as herein envisioned because Sun et al. teaches that one or more of such glycols and/or alcohols may be used in the anhydrous preparations described therein. Furthermore, Sun et al. specifically exemplifies combinations of alcohols and/or glycols in the anhydrous preparations. It would have been obvious to one of ordinary skill in the art to utilize ketoconazole as the antifungal agent in the compositions exemplified in Sun et al. because Sun et al. envisioned miconazole nitrate and ketoconazole to be interchangeable agents therein. Accordingly, one of skill in the art would have been motivated to formulate the composition as claimed in order to prepare a topical antifungal composition with good physical stability and excellent cosmetic attributes suitable for the treatment of athlete's foot, ring worm and jock itch, as taught by Sun et al.

It is noted that the solubility of the ketoconazole is a function of the amounts of components in the system. Accordingly, since the concentrations of components as claimed are the same as taught by the prior art, the degree of solubilization of ketoconazole would be the same in the prior art composition as the composition claimed.

It is noted that the components useful herein are disclosed, generally, as being useful in the invention of Sun et al. Accordingly, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of said components to arrive at the concentrations as herein envisioned. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220, F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955.)

**2) Claims 63 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent No. 5,993,787) in view of Shelton (US 4,083,956), as applied to claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85 above, in further view of U.S. Patent No. 5,208,257 to Kabara.**

Sun et al. is applied as disclosed above. Sun et al. teaches that the use of a chelating agent increasing the wrinkle regulating benefits of the compositions disclosed therein (see column 8, lines 33-41, in particular.) Sun et al. does not specifically teach

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the use of citric acid.

Kabara teaches a topical antimicrobial composition (see abstract, in particular.) Chelating agents, such as citric acid, are taught to be useful herein (see column 7, lines 64 through column 8, line 7, in particular.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize citric acid in a composition of Sun et al. because (1) both Sun et al. and Kabara are directed to antimicrobial compositions; (2) Sun et al. teaches the addition of a chelating agent increases the wrinkle regulating benefits of the compositions disclosed therein; and (3) Kabara teaches citric acid as a chelating agent. One would have been motivated to add citric acid to the composition of Sun et al. in order to increase the wrinkle regulating benefits of the composition, as taught by Sun et al.

**3) Claims 76 and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. 5,993,787) in view of Shelton (US 4,083,956) as applied to claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85 above, in further view of Thornfeldt (U.S. 5,231,087).**

Sun et al. is applied as discussed above. The reference does not specifically teach a method of treating seborrheic dermatitis.

Thornfeldt teaches that *P. ovale* has been shown to play a significant role in seborrheic dermatitis. It is also taught that ketoconazole is known for the treatment of seborrheic dermatitis (see column 2, lines 44-60, in particular.)

It would have been obvious to one of ordinary skill in the art to utilize the composition rendered obvious by Sun et al. in the treatment of *P. ovale* related skin disorder seborrheic dermatitis in humans because (1) the compositions of Sun et al. are disclosed to comprise antifungal agents such as ketoconazole, and (2) Thornfeldt teaches that ketoconazole is capable of treating seborrheic dermatitis. One would have been motivated to treat seborrheic dermatitis with such a composition because, as taught by Thornfeldt, ketoconazole has been reported to improve or clear seborrheic dermatitis lesions in about 75% of patients (see column 2, lines 44-60, in particular.)

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/  
Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627